510(k) Summary

MAR 1 2013

Submitter: Zimmer Trabecular Metal Technology, Inc.
10 Pomeroy Road
Parsippany, New Jersey 07054

Contact Person: Judith Rosen
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Date: November 20, 2012

Trade Name: TM Ardis® Interbody System

Common Name: Intervertebral body fusion device

Classification Name: Intervertebral body fusion device, Lumbar 21 CFR § 888.3080,

Device Panel/Product Code: Orthopedic / MAX

Device Description:
The TM Ardis® Interbody System implant is a convex, straight TLIF or PLIF device for interbody fusion of the anterior column of the spine. TM Ardis is designed for fusing the adjacent bony surfaces and may be used to replace a disc at one or two contiguous levels in L2-S1. The superior and inferior surfaces of the device are textured to provide increased stability and convex to conform to the vertebral endplates. The device also has two slots on the posterior end to mate with the insertion instrument. The TM Ardis device is wholly comprised of Trabecular Metal Porous Tantalum. Surgical instrumentation for use with the proposed system is fabricated from surgical grade stainless steel and other applicable materials. TM Ardis Interbody System was cleared via 510(k) number K113561 on May 29, 2012.

The TM Ardis® Inserter instrument, that is the subject of this premarket notification, is intended for use with the TM Ardis® Interbody System. This instrument is designed specifically for use with the TM Ardis® Implants and is considered an accessory to the implants.

Indications for Use:
The TM Ardis® Interbody System is indicated for use with autogenous bone graft as an intervertebral body fusion device at one or two contiguous levels in the lumbosacral region (L2-S1) in the treatment of degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. Patients with previous non-fusion spinal surgery at involved level may be treated with the device. Patients should be skeletally mature and have had six months of non-operative treatment.

The TM Ardis® Interbody System device is implanted using a posterior or transforaminal approach and is intended to be used singly or in pairs with supplemental fixation.

Device Technological Characteristics and Comparison to Predicate Device(s):
Zimmer TMT, Inc. has submitted documentation demonstrating the substantial equivalence of the modified TM Ardis® Inserter instrument to the original version of the device included in K113561.

The unmodified and modified versions of the TM Ardis® Inserter instrument differ by a design change to the Inserter Locking Nut component and a dimentional change of the Inserter Body (Locking Nut) Housing. These changes provide additional leverage to release the implant from the instrument and reduce axial clearance between the Locking Nut and the Housing of the Inserter Body.

Both unmodified and modified versions of the TM Ardis® Inserter instrument have the same intended use, operate on the same technological principles, are manufactured from the same material (17-4 stainless steel), are cleaned and sterilized in the same manner with the same parameters, and have similar designs. The steel utilized for both versions meet ASTM A564/A564M: *Specification for Hot-Rolled and Cold-Finished Age-Hardening Stainless Steel and Heat-Resisting Steel Bars and Shapes*.

Performance Data:
The results of testing performed demonstrated that acceptance criteria were met in both Design Verification and Design Validation Testing and the modified TM Ardis Inserter adequately meet the requirements established in the design specifications for its mechanical performance. This testing demonstrated that the modified device is substantially equivalent to the predicate device.

Substantial Equivalence:
Zimmer TMT, Inc. has submitted documentation demonstrating the substantial equivalence of the modified TM Ardis® Inserter instrument to the original unmodified version of the device. The proposed TM Ardis® Inserter instrument is similar to the predicate version of the instrument in general form, materials, functional, sterilization and cleaning, and intended use. As demonstrated by supporting tests and descriptions, this design modification does not present new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 1, 2013

Zimmer Trabecular Metal Technology, Incorporated
% Ms. Judith Rosen
Senior Regulatory Affairs Specialist
10 Pomeroy Road
Parsippany, New Jersey 07054

Re: K123602
Trade/Device Name: TM Ardis® Interbody System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: February 6, 2013
Received: February 7, 2013

Dear Ms. Rosen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123602

Device Name: TM Ardis® Interbody System

Indications for Use:

The TM Ardis® Interbody System is indicated for use with autogenous bone graft as an intervertebral body fusion device at one or two contiguous levels in the lumbosacral region (L2-S1) in the treatment of degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. Patients with previous non-fusion spinal surgery at involved level may be treated with the device. Patients should be skeletally mature and have had six months of non-operative treatment.

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Prescription Use __X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anton E. Dmitriev, PhD
Division of Orthopedic Devices